SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 500—GENERAL

Subpart A [Reserved]

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Sec.

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AUTHORITY: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371.

SOURCE: 40 FR 13802, Mar. 27, 1975, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Specific Administrative Rulings and Decisions

§ 500.23 Thermally processed low-acid foods packaged in hermetically sealed containers.

The provisions of part 113 of this chapter shall apply to the manufacture, processing or packing of low-acid foods in hermetically sealed containers, and intended for use as food for animals.

[61 FR 37681, July 19, 1996]

§ 500.24 Emergency permit control.

The provisions of part 108 of this chapter shall apply to the issuance of emergency control permits for the manufacturer or packer of thermally processed low-acid foods packaged in hermetically sealed containers, and intended for use as food for animals.

[61 FR 37681, July 19, 1996]

§ 500.25 Anthelmintic drugs for use in animals.

(a) The Commissioner of Food and Drugs has determined that, in order to assure that anthelmintic drugs, including animal feeds bearing or containing such drugs, which do not carry the prescription statement are labeled to provide adequate directions for their effective use, labeling of these anthelmintic drugs shall bear, in addition to other required information, a statement that a veterinarian should be consulted for assistance in the diagnosis, treatment, and control of parasitism.

(b) The label and any labeling furnishing or purporting to furnish directions for use, shall bear conspicuously the following statement: ''Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.''

(c) For drugs covered by approved new animal drug applications, the labeling revisions required for compliance with this section may be placed into effect without prior approval as provided for in § 514.8 (d) and (e) of this chapter. For animal feeds bearing or containing anthelmintic drugs covered by approved applications, the labeling revisions required for compliance with this section may be placed into effect without the submission of supplemental applications as provided for in § 514.9 of this chapter.

(d) Labeling revisions required for compliance with this section shall be placed into effect by February 25, 1975, following which, any such drugs that are introduced into interstate commerce and not in compliance with this section will be subject to regulatory proceedings.

§ 500.26 Timed-release dosage form drugs.

(a) Drugs are being offered in dosage forms that are designed to release the active ingredients over a prolonged period of time. There is a possibility of unsafe overdosage or ineffective dosage if such products are improperly made and the active ingredients are released at one time, over too short or too long a period of time, or not released at all. Drugs marketed in this form, which are referred to by such terms as timed-release, controlled-release, prolonged-release, sustained-release, or delayed-release drugs, are regarded as new animal drugs within the meaning of section 201(v) of the Federal Food, Drug, and Cosmetic Act.

(b) Timed-release dosage form animal drugs that are introduced into interstate commerce are deemed to be adulterated within the meaning of section 501(a)(5) of the act and subject to regulatory action unless such animal drug is the subject of an approved new animal drug application as required by paragraph (a) of this section.

(c) The fact that the labeling of this kind of drug may claim delayed, prolonged, controlled, or sustained-release of all or only some of the active ingredients does not affect the new animal drug status of such articles. A new animal drug application is required in any such case.

(d) New animal drug applications for timed-release dosage form animal drugs must contain, among other things, data to demonstrate safety and effectiveness by establishing that the article is manufactured using procedures and controls to ensure release of the total dosage at a safe and effective rate. Data submitted in the new animal drug application must demonstrate that the formulation of the drug and the procedures used in its manufacture will ensure release of the active ingredient(s) of the drug at a safe and effective rate and that these release characteristics will be maintained until the expiration date of the drug. When the drug is intended for use in food-producing animals, data submitted must also demonstrate that, with respect to possible residues of the drug, food derived from treated animals is safe for consumption.

[42 FR 8635, Feb. 11, 1977, as amended at 60 FR 38480, July 27, 1995]

§ 500.27 Methylene blue-containing drugs for use in animals.

(a) New information requires a reevaluation of the status of drugs containing methylene blue (tetramethylthionine chloride) for oral use in cats or dogs.

(1)(i) It has been demonstrated that two orally administered urinary antiseptic-antispasmodic preparations that contained methylene blue cause Heinz body hemolytic anemia in cats when used according to label directions. The specific cause of the reaction was determined to be the methylene blue contained in the preparations. The reaction can be severe enough to cause death of treated animals.

(ii) The Heinz body hemolytic anemia reaction to methylene blue has also been demonstrated in dogs under laboratory conditions. The precise mechanism by which methylene blue produces the characteristic erythrocytic inclusion bodies (Heinz bodies) and associated hemolytic anemia is unclear.

(2) The effectiveness of orally administered methylene blue as a urinary antiseptic is open to question. It appears that following oral administration, methylene blue is poorly and erratically absorbed and also slowly and erratically excreted in the urine. Studies